MAY 2 4 2004

K041295

ATTACHMENT 7 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-0791
Contact Person: John King
Regulatory Affairs

2. **Name of the Device**

Trade Name:	Straumann RN synOcta UCLA Gold Abutment
Common Name:	Dental implant abutment
Classification Name:	Endosseous dental implants 21 CFR 872.3640

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

Straumann 1.5mm synOcta Abutment with Gold Coping (K022859)

4. **Description of the Device**

The ITI Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially, or fully edentulous patients. The system consists of a variety of dental implants, abutments, and surgical and prosthetic parts and instruments. The device covered by this submission is an abutment.

The basal portion of the abutment has an inset octagonal design. The abutment is seated in the implant with a screw, which is mounted in the basal portion of the abutment. The abutment is used for cemented and screw restorations.

5. **Intended Use of the Device**

The abutment is placed into the dental implant to provide support for a prosthetic restoration such as a crown or bridge.

6. Basis for Substantial Equivalence

The Straumann RN synOcta UCLA gold abutment is substantially equivalent in intended use, material, and design to the 1.5 mm synOcta abutments and gold copings cleared under K022859. The intended use of the subject abutment is identical to the predicate abutment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2004

Institut Straumann AG
C/O Mr. John King
Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K041295
Trade/Device Name: RN SynOcta UCLA Gold Abutment For the Straumann Dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: May 13, 2004
Received: May 14, 2004

Dear Mr. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

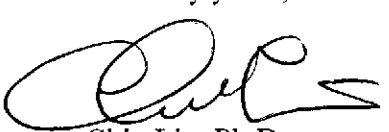
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041295

Device Name: RN synOcta UCLA Gold Abutment

Indications for Use:

Abutments are intended to be placed into dental bridges to provide support for prosthetic reconstructions such as crowns or bridges.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041295